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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,787	05/23/2005	Brian F. O'Dowd	3477-110	3131
20792	7590	11/30/2006	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			ULM, JOHN D	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,787	O'DOWD ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 8, 11, 17- 20, 27, 30, 31 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/9/05, 4/26/06</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1, 2, 4-6, 8, 11, 16-20, 27, 30, 31, 34, 37-41, 43, 46-49, 56, 59, 61, 62, 64-66, 68, 74- 77, 84, 87, 90-93, 96, 97, 99-101, 103, 106, 112-115 and 122 .

Continuation of Disposition of Claims: Claims withdrawn from consideration are 37-41, 43, 46-49, 56, 59, 61, 62, 64-66, 68, 74-77, 84, 87, 90-93, 96, 97, 99-101, 103, 106, 112-115 and 122.

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1) Claims 1,2, 4 to 6, 8, 11, 16 to 20, 27, 30, 31, 34, 37 to 41,43, 46 to 49, 56, 59, 61, 62, 64 to 66, 68, 74 to 77, 84, 87, 90 to 93, 96, 97, 99 to 101, 103, 106, 112 to 115 and 122 are pending in the instant application.

2) Claims 61, 62, 64 to 66, 68, 74 to 77, 84, 87, 90 to 93, 96, 97, 99 to 101, 103, 106, 112 to 115 and 122 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 22 June of 2006. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement with respect to these claims, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3) Claims 37 to 41,43, 46 to 49, 56 and 59 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 22 June of 2006. The traversal is on the grounds that a search of the methods of claims 1 and 37 in a single applicant would not constitute an undue burden because each of those methods employs a cell is transfected with a nucleotide sequence encoding a transmembrane protein containing at least one nuclear localisation sequence (NLS) wherein the distribution of the expressed protein in a cell contacted with the candidate compound is compared with its distribution in a transfected control cell not contacted with the compound.

This has not been found persuasive because a method employing a transfected cell expressing a heterologous transmembrane protein comprising a nuclear

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translocation sequence wherein the distribution of the receptor is determined is not a distinguishing inventive concept, as shown by the Conway et al. publication (J. Cellu. Phys. 189(3): 341-355, Dec.2001) and Chen et al. publication (Am. J. Physical Renal; Physiol. 279:F440-F448, 2000), cited in the information disclosure statement filed 09 August of 2005. The method of claim 1 and the method of claim 37 are only distinct from the prior art, and one another, by the parameter being measured and the method measurement. Therefore, these two methods reflect a different distinguishing inventive concept.

The requirement is still deemed proper and is therefore made FINAL.

4) Applicant is advised that, should the elected claims be amended to recite a method that employs a distinguishing product, Applicant is entitled to present claims corresponding to claims 37 to 41,43, 46 to 49, 56 and 59 wherein those claims require that distinguishing product.

5) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code in line 30 on page 15 and line 15 on page 27, for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01(p), which states that:

“When a patent application with embedded hyperlinks and/or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site.

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USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. If hyperlinks and/or other forms of browser-executable code are embedded in the text of the patent application, examiners should object to the specification and indicate to applicants that the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion.”

Correction is required.

6) The drawings in the instant application do not comply with 37 C.F.R. § 1.821(d), which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. M.P.E.P. 2422.02 expressly states that “when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier (“SEQ ID NO:X”) must be used, either in the drawing or in the Brief Description of the Drawings”. Figure 1 of the instant application presents an amino acid sequence without employing the required sequence identifier. Correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7) Claims 1,2, 4 to 6, 8, 11, 17 to 20, 27, 30, 31 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and/or use the invention. It is clear from the express limitations of claim 8 that the instant claims are intended to encompass a method that employs a prokaryotic host cell. The summary of the invention on page 9 of the instant specification states that “[t]he inventors have shown that the incorporation of a nuclear localisation sequence (NLS) into a transmembrane protein (not containing an endogenous functional NLS) routes the protein from the cell surface into the nucleus of a cell in a time-dependent and ligand-independent manner”. The claimed method requires a difference between the distribution of transmembrane protein within a cell expressing upon exposure to a compound that interacts with that protein and the distribution of that protein in a cell that has not been exposed to that compound. One of ordinary skill in the art of receptor biology would have absolutely no reason to believe that the incorporation of an NLS into a transmembrane protein will have any effect at all on the localization of that protein in a prokaryotic cell upon exposure to a compound that interacts with that protein since a prokaryotic cell, by definition, has no nucleus. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc. v. Novo Nordisk*, 42 USPQ 2d 100, (CAFC 1997), the court held that:

“[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable” and that “[t]ossing out the mere germ of an idea does not constitute enabling disclosure”. The court further stated that “when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the

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disclosure related to the process is within the skill of the art”, “[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement”.

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed method with a prokaryotic host cell with any reasonable expectation of success.

Claim 16 has not been included with the above rejection because it depends from a cancelled claim and, therefore, the metes and bounds of claim 16 are undeterminable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8) Claims 8, 11, 16, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8.1) Claims 8 and 11 are vague and indefinite because the phrase "optionally" renders each of these claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

8.2) Claim 16 is vague and indefinite because it depends from a cancelled claim.

8.3) Claims 19 and 20 are vague and indefinite because there is no antecedent basis for “dopamine D1 receptor, dopamine D2 receptor...”, dopamine transporter”, etc. There are a plurality of proteins known in the art as D1 dopamine receptors, D2

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dopamine receptors etc. Therefore, these claims should refer to "a dopamine D1 receptor", "a dopamine D2 receptor", "a dopamine transporter", etc.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9) Claims 1, 2, 4, 8, 17, 18, 30, 31 and 34 are rejected under 35

U.S.C. 102(a) as being clearly anticipated by the Conway et al. publication (J. Cellu.

Phys. 189(3): 341-355, Dec.2001, cited by Applicant).

10) Claims 1, 2, 4, 8, 17, 18, 30, 31 and 34 are rejected under 35

U.S.C. 102(b) as being clearly anticipated by the Chen et al. publication (Am. J.

Physical Renal; Physiol. 279:F440-F448, 2000, cited by Applicant).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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